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PATENT & TRADEMARK OFFICE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF APPEALS

Appellant:	Louis Woo	)
		)
Serial No:	10/685,809	) Art Unit: 3767
		)
Filed:	October 16, 2003	) Examiner: Anderson, Michael J.
		)
For:	DILATORS	) Attorney Docket: 0119/0017
		)
		)

APPEAL BRIEF

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REAL PARTY IN INTEREST

The real party in interest of the subject application is Smiths Group plc to whom the inventor assigned his invention per an Assignment recorded October 16, 2003 on Reel 014614, Frame 0681 at the Assignment Branch of the U.S. Patent and Trademark Office.

RELATED APPEALS AND INTERFERENCES

As far as is known, there are no appeals or interferences that are related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

STATUS OF CLAIMS

Claims 1-12 are pending in the application, and are being appealed herein.

Claims 1-12 were rejected in the Office Action dated February 24, 2009. Being appealed claims 1-12 are reproduced in the Claims Appendix.

STATUS OF AMENDMENTS

There was no amendment filed in response to the Office Action dated February 24, 2009.

SUMMARY OF THE CLAIMED SUBJECT MATTER

Independent claim 1 is directed to a tracheostomy dilator (Figs. 1, 4) that includes a patient end region (3) that is curved, tapered and adapted for insertion through a tracheostomy to expand the tracheostomy as it is being inserted, and a handle region (5) at an end of the dilator opposite to the patient end region. The handle region is curved in an opposite sense from the patient end region. [Page 4, lines 6-10]

Dependent claim 2 defines the dilator to have a passage (10) that extends along the dilator for receiving a guide member. [Fig. 2; page 4, lines 11-12]

Claim 3 depends from claim 2 which in turn depends from claim 1, and recites a tip (2) of the patient end region that provides a substantially stepless transition with an outer surface of the guide member. [Figs. 1, 3; page 5, lines 7-9]

Claim 4 defines the handle region (5) to have a substantially constant diameter along its length. [Figs. 1, 3; page 4, line 4]

Claim 5 defines the handle region (5) to have surface formations (9) to enhance the grip. [Figs. 1-, 3; page 4, line 5]

Claim 6 defines the dilator to be molded from a plastics material. [Page 3, lines 7-8]

Claim 7 defines the plastics material to have a Shore hardness of substantially 90A. [Page 3, lines 7-8]

Claim 8 defines the radius of the curvature of the handle region (5) to be substantially the same as that of the patient end region (3). [Fig. 1; page 4, lines 8-9]

Claim 9 defines the radius of the curvature of the patient end (3) to be about 90mm. [Page 4, line 8]

Claim 10 defines the dilator of claim 1 to include a coating of hydrophillic material along its patient end region. [Page 4, lines 15-16]

Independent claim 11 recites a tracheostomy dilator that has one end providing a handle region (5) and an opposite end providing a flexible, tapered patient end region (3) for insertion to the trachea. The dilator is defined to be smoothly curved along substantially its entire length with an S shape. [Fig. 1, page 3, lines 12-15 and page 4, lines 6-10]

Independent claim 12 recites a tracheostomy dilator that includes a patient end rejection (3) that is tapered along its length [page 3, lines 14-15], an intermediate region (4) that tapers along its length substantially less than the patient end region [page 4, lines 1-3], and a handle end region (5) that has a substantially constant diameter along its length [page 4, lines 4-5]. The dilator has a passage (10) that extends within it and opens at a tip (2) of the patient end rejection to accommodate a guide member along which the dilator is inserted into the trachea [page 2, line 12; page 14, lines 11-12]. The wall thickness of the patient end region is reduced towards the patient end tip so as to provide a smooth transition with an outer surface of the guide member [page 4, lines 12-14; page 5, lines 6-9], and the dilator is curved along substantially its entire length to an S shape so that the dilator can be held in the hand and inserted into the trachea ergonomically [Fig. 4, page 4, lines 6-10; page 5, line 12 to page 6, line 2].

Simply put, the at issue tracheostomy tube dilator is an S shaped dilator that smoothly curves along substantially its entire length, with its handle region curving in an opposite sense as its patient region.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1-12 stand rejected under 35 U.S.C. §103 (a) as being unpatentable over Ciaglia et al. publication (US 2002/0066453) in view of Kuhn (US 3,363,629).

ARGUMENT

35 U.S.C. 103(a) rejection of Claims 1-12 under Ciaglia et al. (US 2002/0066453) in view of Kuhn (US 3363629)

Independent claim 1 recites that the handle region of the claimed tracheostomy dilator is curved in an opposite sense from the patient end region.

Independent claim 11 requires that the dilator be smoothly curved along substantially its entire length with an S shape.

Independent claim 12 requires that the dilator be curved substantially along its entire length to a S shape so that the dilator can be held in the hand and inserted into the trachea ergonomically.

Even though conceding that Ciaglia fails to disclose a handle region of a dilator curved in an opposite sense as the patient end region, the examiner nonetheless has relied on paragraphs 0006 and 0019 of Ciaglia to argue that there is provision in Ciaglia to support the Ciaglia handle "to be curved in an opposite direction of the distal portion." The examiner further asserts that this is what was pointed out by the Applicant in the previous appeal briefs.[1] Nothing is further from the facts.

Paragraphs 0006 and 0019 of Ciaglia are reproduced hereinbelow:

> "The single dilator includes a soft, pliant tapered tip identical in shape and size and in tip inner diameter to those of the prior art dilators, and additionally includes a curved distal portion extending from the tapered tip toward the proximal end, and the **generally linear shaft**. The curved distal portion is tapered to extend from a diameter of 12 french (for example) adjacent the tapered tip, to a diameter of 38 french adjacent **the linear shaft**. Preferably both the curvature and the taper of the curved

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[1] In the paragraph bridging pages 3 and 4 of the February 24, 2008 Office Action, the Examiner states: "(Provisions are provided (pp[0006, 0019]) for the handle to be curved in an opposite direction of the distal portion. Since, as pointed out in applicants [sic] appeal brief [sic] of 5/29/2008 and 11/10/2008, Ciaglia discloses (paragraph [0019]) ..."

> tapered distal portion from the distal tip to the shaft is gradual with no discontinuities. Also preferably, the curved tapered distal portion has a gradual transition in flexibility from very flexible at the short distal tip portion to generally rigid at **the generally linear shaft portion**, such as by gradually changing its wall thickness." [0006]
>
> "The curvature of curved tapered distal portion 16 may be a series of curves of different radii, or a complex curve, from distal end 20 at least to demarcation 22. The portion of dilator 10 between demarcation 22 and insertion limit 26 will extend, during use of the dilator, between the outer skin of the patient and the inside or anterior surface of the trachea of the patient. Also, the optimum curvature may be within a range such that the outer surfaces are within a zone of tolerance. While not susceptible of a precise mathematic definition, it is preferred that the curvature be complementary to the curvature of conventional curved tracheostomy tubes." [0019] [Underlines added with terms bolded.]

If anything, paragraph 0006 of Ciaglia confirms that the curved distal portion (16) extends from the distal end (20) to the **linear shaft** (12). Putting it simply, shaft (12) of the Ciaglia device is linear. This is also clearly shown in Figs. 2 and 3 of Ciaglia. As for paragraph 0019, Ciaglia discloses there that the curved tapered distal portion (16) may be formed from a series of curves of different radii, and that the curvature of the distal portion may be complementary to the curvature of conventional curved tracheostomy tubes. That the Ciaglia distal portion may be formed from curves of different radii has nothing to do with the linear shaft of the Ciaglia dilator. If anything, it confirms that it is only the distal portion of Ciaglia dilator that is curved. That the curvature of the distal portion of the Ciaglia dilator may be complementary to curved tracheostomy tubes also has no bearing on the linear shaft of the Ciaglia dilator. This is so that after the desired opening is made by the Ciaglia dilator at the trachea of the patient, a complementary curved tracheostomy tube may be inserted through the widened tracheal opening into the patient (see paragraph 0024).

Based on this mistaken premise, the examiner next asserts that Kuhn "discloses (figure 1) wherein said handle region is curved in an opposite sense from said patient end region. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the tracheostomy dilator of Ciaglia as disclosed by Kuhn for easy insertion without damage to the vocal cavity and in the trachea (Kuhn, column 1, lines 22-54)."[2]

The device described by Kuhn is completely different to the dilator of the present application. It is submitted that the examiner is not justified in combining the teaching of Kuhn and Ciaglia.

To begin, Kuhn does not describe a dilator. Rather, the Kuhn device is an endotracheal breathing tube designed to be inserted through the mouth of the patient so that one end locates in the patient's trachea and the other end projects from the patient's mouth. The Kuhn device is curved to follow the shape of the upper trachea, pharyngeal space and oral cavity, and to project out of the mouth in a desired direction (column 1, lines 45-48 of Kuhn). The "handle region" asserted by the examiner for the Kuhn device is actually the machine end of the Kuhn device whereto a ventilator may be connected to supply air to the patient.

The dilator of the present invention, by contrast, is a surgical instrument designed to expand tissue in the region of a surgically-made opening through the tracheal cartilages at the neck of the patient so that the opening is expanded sufficiently to receive a tracheostomy tube. Tracheostomy tubes are a very different shape from endotracheal tubes because of the different paths taken. Tracheostomy tubes are usually of a right-angled, L shape with one short end locating in the trachea and the opposite end projecting at right angles out through the tracheostomy opening in the neck of the patient at substantially collar level.

The purpose of an endotracheal tube of the kind described by Kuhn is to provide a conduit for supplying gas to a patient in a safe manner.

The purpose of a tracheostomy dilator of the kind of the present invention is very different in that it is for expanding a surgically-made cut opening through the neck tissue and the tracheal cartilages so that a tracheostomy tube may be inserted into the trachea.

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[2] Last line, page 3 - line 4, page 4 of the February 24, 2009 Office Action.

The shape, therefore, of Kuhn's endotracheal tube is selected to conform to the anatomy for reduced trauma to the delicate tracheal lining. The shape of the tracheostomy dilator of the present invention, by contrast, is selected for facilitating the safe expansion of the tissue in the region of the trachea.

Also, the endotracheal tube of Kuhn, once it is inserted through the mouth into the trachea of the patient, is held thereat so that the patient may breathe. On the other hand, once the surgically-made cut opening through the neck tissue and the tracheal cartilages is expanded thereby, the tracheostomy dilator is removed and a tracheostomy tube, mounted on an introducer, is slid into the trachea by way of the expanded opening (page 5, lines 10-11 of specification).

Moreover, the above underlined reasoning which the examiner relies on to combine Ciaglia with Kuhn is misplaced since the vocal cavity does in fact get damaged when an opening is first surgically made at the neck tissue and tracheal cartilages of the patient and a tracheostomy dilator then is used to expand the surgically-made cut opening through the neck tissue and the tracheal cartilages.

There is therefore no connection between the shape of endotracheal tubes and tracheostomy dilators and no reason why anyone would think that the field of endotracheal tubes had anything to teach someone seeking to design an improved tracheostomy dilator. Thus, there is no "apparent reason", as required by the courts, for a person having ordinary skill in the art to combine Ciaglia and Kuhn per assertion by the examiner.[3]

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[3] In *KSR Int'l Cov Teleflex Inc.*, 550 US ____, 127 S Ct. 1727, 167 L. Ed. 2d 705 (2007), the Court holds that there must be "an apparent reason to combine the known elements in the fashion claimed by the patent at issue" if "interrelated teachings of multiple patents" and other factors were to be used to argue that the claimed subject matter is obvious. At page 14 of slip opinion issued April 30, 2007.

In *Alza Corp. v. Mylan Lab*, 464 F.3d 1286, 1290-1291 (2006)[4] the CAFC states: "To reach a non-hindsight driven conclusion as to whether a person having ordinary skill in the art at the time of the invention would have viewed the subject matter as a whole to have been obvious in view of multiple references, the Board must provide some rationale, articulation or reasoned basis to explain why the conclusion of obviousness is correct. ... However, rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness."

In the light of guidance provided by the courts, appellant respectfully submits that the examiner has not provided any rational underpinning to support his obviousness rejection, for there is nothing in Ciaglia and Kuhn that suggests that those references could be combined per asserted by the examiner. Indeed, the examiner himself has debunked his own reasoning that by combining Kuhn with Ciaglia, there would not be damage to the vocal cavity -- when in fact, the use of a tracheostomy dilator does damage the vocal cavity of the patient.

In view of the above, appellant respectfully submits that the rejection of independent claims 1, 11 and 12, and claims 4-10 dependent from claim 1, is without merit and not sustainable.

Conclusion

For the reasons pointed out above, appellant respectfully submits that the pending claims on appeal are patentably distinguishable over the cited references and that the examiner's rejection accordingly is without merit and not sustainable. The Board is therefore respectfully requested to reverse the examiner's rejection.

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[4] The *Alza* case was cited by the Supreme Court in *KSR Int'l.* There the Court noted approvingly the *Alza* court's obviousness analysis of the claimed invention. *Id* at 18. The Court also confirmed the requirement for "some articulated reasoning with some rational underpinning" to support the legal conclusion of obviousness. *Id* at 14.

Respectfully submitted,

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CLAIMS APPENDIX

1. A tracheostomy dilator comprising: a patient end region, said patient end region being curved, tapered and adapted for insertion through a tracheostomy to expand the tracheostomy as it is inserted; and a handle region at an end of the dilator opposite said patient end region, wherein said handle region is curved in an opposite sense from said patient end region.

2. A dilator according to Claim 1, wherein said dilator has a passage extending along it for receiving a guide member.

3. A dilator according to Claim 2, wherein a tip of said patient end region provides a substantially stepless transition with an outer surface of said guide member.

4. A dilator according to Claim 1, wherein said handle region has a substantially constant diameter along its length.

5. A dilator according to Claim 1, wherein said handle region has surface formations adapted to enhance grip.

6. A dilator according to Claim 1, wherein said dilator is moulded of a plastics material.

7. A dilator according to Claim 6, wherein said plastics material has a Shore hardness of substantially 90A.

8. A dilator according to Claim 1, wherein the radius of a curvature of said handle region is substantially the same as that of said patient end region.

9. A dilator according to Claim 1, wherein the radius of curvature of said patient end is about 90mm.

10. A dilator according to Claim 1 including a coating of a hydrophilic material along its patient end region.

11. A tracheostomy dilator comprising one end providing a handle region and an opposite end providing a flexible, tapered patient end region for insertion to the trachea, wherein said dilator is smoothly curved along substantially its entire length with an S shape.

12. A tracheostomy dilator comprising: a patient end region, said patient end region tapering along its length; an intermediate region, said intermediate region tapering along its length substantially less than said patient end region; and a handle end region, said handle end region having a substantially constant diameter along its length, wherein said dilator has a passage extending within it and opening at a tip of said patient end region to accommodate a guide member along which said dilator is inserted to the trachea, wherein the wall thickness of said patient end region reduces towards a patient end tip such as to form a smooth transition with an outer surface of said guide member, and wherein said dilator is curved along substantially its entire length to an S shape so that the dilator can be held in the hand and inserted into the trachea ergonomically.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.